IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIVAGEN PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 24-846-GBW
	)	
AMNEAL PHARMACEUTICALS, INC., AMNEAL PHARMACEUTICALS of NEW YORK, LLC, AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS PVT LTD., and AMNEAL EU, LTD.	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

NIVAGEN PHARMACEUTICALS, INC.'S BRIEF IN SUPPORT OF ITS MOTION TO DISMISS AMNEAL PHARMACEUTICALS LLC'S COUNTERCLAIMS V AND VI, AND STRIKE DEFENDANTS' SECOND, THIRD, AND SEVENTEENTH AFFIRMATIVE DEFENSES, REGARDING ALLEGED "INEQUITABLE CONDUCT" AND "WRONGFUL ENJOINMENT"

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I. INTRODUCTION AND THE ISSUES PRESENTED

Plaintiff Nivagen Pharmaceuticals, Inc. ("Nivagen") holds two patents on sterile ready-to-use ("RTU") potassium phosphate products, but the drug application on its RTU product is still under FDA review. The Amneal Defendants recently launched a similar RTU potassium phosphate product in the U.S. (D.I. 91, Answer to Nivagen's Second Amended Complaint, at 30, ¶ 101). Nivagen sued Defendants for patent infringement. Defendants answered and asserted counterclaims. (*Id.* at 36-69).

Nivagen moves to dismiss Counterclaim V with prejudice and strike Defendants' Second, Third, and Seventeenth Affirmative Defenses, which are all based on allegations of "inequitable conduct." Amneal accused "Named Inventors and Prosecutors" of withholding the "FK PI" reference from the patent examiner. (*Id.* at 66, ¶ 120).[1] Amneal's "inequitable conduct" allegations merely repackaged what Amneal had already presented, and lost on, during the temporary restraining order and preliminary injunction ("TRO/PI") proceedings in this case. (D.I. 28 (Amneal Opposition Brief to TRO/PI), at 12-14; D.I. 61 (Memorandum Opinion granting TRO/PI), at 10 n. 3).[2] The Court's previous ruling regarding FK PI's lack of materiality to the Nivagen patents (because FK PI did not disclose any sterile RTU product) should be given preclusive effect, to bar Amneal's repeated but futile allegations of "inequitable conduct."

[1] Only Amneal Pharmaceuticals LLC filed Counterclaims V and VI subject to this Motion. Nivagen refers to all Amneal Defendants, individually or collectively, as "Amneal" in this Motion. The disposition of this Motion is not hinged on which company filed Counterclaims V and VI.

[2] Public record and documents forming the basis of a claim (such as the TRO/PI motion hearing transcript attached to D.I. 91 as Ex. F) can be considered by the Court for a motion to dismiss. "[D]ocket sheets, pleadings, and docket entries, are matters of public record which the court may properly consider in ruling on a Rule 12(b)(6) motion." *Rumanek v. Fallon*, C.A. No. 17-123-CCC, 2018 WL 4441458, at *17 n. 1 (D. Del. 2018) (citing *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010)). The Court may consider public record, "matters incorporated by reference or integral to the claim," and "items appearing in the record of the case." *Zerby v. Waltz*, No. 1:16-cv-00383-YK, 2017 WL 386616, at *3 (M.D. Pa. 2017).

Nivagen will also show that the factual allegations in Counterclaim V, even if analyzed *de novo*, still do not make it plausible that FK PI would have been material. No discovery is possible in this case to make FK PI material to the prosecution of the Nivagen patents. Counterclaim V is also completely deficient on pleading the "who," "what" and "why" with the required particularity. Amneal never alleged a single improper action by a specific individual. Amneal did not present any factual allegations on anyone's knowledge and intent. Therefore, Amneal's "inequitable conduct"-based defenses and Counterclaim V must be stricken and dismissed—with prejudice.

Nivagen also moves to dismiss Counterclaim VI with prejudice. Amneal alleged that Nivagen obtained the TRO/PI by "misleading arguments and/or information to the Court on issues relating to irreparable harm …."[3] (D.I. 91, at 66, ¶ 122). Amneal styled Counterclaim VI as a "declaratory judgment" count but seeks unspecified damages for "wrongful enjoinment." (*Id.* at 68, ¶ 137). The preliminary injunctive relief in this case included both a TRO and a PI. (D.I. 62 at ¶ 1; D.I. 86). Because no injunction bond was posted, and because of the effect of the TRO, Amneal cannot recover any damages for "wrongful injunction." Furthermore, Nivagen will show, based on the TRO/PI motion hearing transcript and the Court's TRO/PI opinion, (D.I. 61), that none of the alleged misrepresentations had contributed to the granting of the injunctive relief. Counterclaim VI should be dismissed with prejudice, because this counterclaim is not only legally impermissible due to the TRO, but also lacks any allegation of the necessary causative link for Amneal to claim any damages.

[3] Amneal's allegations of "misleading arguments and/or information to the Court" cannot be proven. For the purpose of this Motion, Nivagen focuses on the deficiencies in Amneal's pleading.

II. PREVIOUS PROCEEDINGS IN THIS CASE

Nivagen spent years developing a novel RTU product, and obtained two patents. (*See* D.I. 61, at 2-3). Through these efforts, Nivagen hoped to rebrand itself as an innovator in the field. (*Id.* at 23). However, before Nivagen could clear the regulatory requirement for, manufacture, and sell its RTU product, it learned that Amneal had a similar (and later adjudicated by this Court as likely infringing the Nivagen patents) product under review at the FDA, so Nivagen filed this patent infringement lawsuit against Amneal on July 19, 2024. (*Id.* at 2, 7; *see also* D.I. 1).

Amneal received final FDA approval for its RTU product several days after this lawsuit was originally filed, and, despite the pending lawsuit, announced an imminent product launch. (*Id.* at 3). Nivagen moved for a TRO and a PI. (D.I. 12; D.I. 12-1). After a hearing, the Court ordered the parties to submit briefing concerning the bond amount for any preliminary injunctive relief. (D.I. 53). The parties submitted their letter briefs on September 23, 2024. (D.I. 57; D.I. 59). Also on September 23rd, the Court granted both a TRO and a PI. (D.I. 62, at ¶ 1). The Court confirmed in its Memorandum Opinion that both a TRO and a PI were "granted herein." (D.I. 61, at 29). On September 24, 2024, the Court set a bond at $30 million. (D.I. 63).

On September 25, 2024, Nivagen sent a letter informing the Court that it could not finance a $30 million bond, and it would not have cash on hand to post the bond before it started to sell its RTU product. (D.I. 66, at 1). Instead of a $30 million bond to cover 3.25 years of Amneal's potential damages, Nivagen urged the Court to consider a bond of $2.55 million to cover six months of injunction. (*Id.* at 2). The lower bond amount in this letter was based on *Amneal's* estimate of its potential damages for six months, and Nivagen offered to renew and adjust the bond periodically to ensure ongoing coverage for Amneal. (*Id.*). The Court rejected Nivagen's proposal. (D.I. 70, at 2). On October 1, 2024, Nivagen informed the Court that it could not post

the bond. (D.I. 76). No bond was posted. The Court terminated both the TRO and the PI on October 15, 2024. (D.I. 86).

Amneal launched its RTU product in late October. (D.I. 91, at 20, ¶ 60). Nivagen then filed its Second Amended Complaint alleging patent infringement and seeking damages. (D.I. 88). Amneal filed their Answer and Counterclaims on December 6, 2024. (D.I. 91).

III. LEGAL STANDARDS

A. Motion to Dismiss

The Third Circuit employs a three-step inquiry for the sufficiency of a complaint to withstand a Rule 12(b)(6) challenge. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130-131 (3d Cir. 2010). First, "the court must take note of the elements a plaintiff must plead to state a claim." *Id.* at 130. Next, the factual and legal elements of a claim must be separated; only "well-pleaded facts are accepted as true," while mere legal conclusions should be disregarded. *Id.* at 131-132; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice"). The well-pled factual allegations must then be determined sufficient to show a "plausible claim for relief," or the claim must be dismissed. *Iqbal*, 556 U.S. at 678-79.

B. Motion to Strike

"An affirmative defense can be stricken if it cannot possibly prevent recovery under any pled or inferable set of facts." *Eagle View Technologies, Inc. v. Xactware Sols., Inc.*, 325 F.R.D. 90, 102 (D.N.J. 2018). If an affirmative defense is "tied to the inequitable conduct counterclaim" that is not sufficient, "the insufficiencies of the defense are clearly apparent," and the defense must be stricken. *Id.*

C. Heightened Pleading Standard for "Inequitable Conduct"

An "inequitable conduct" claim must cover two elements: (1) "a misrepresentation or omission material to patentability" has occurred, and (2) "a specific individual under a duty of candor" committed that offending act with a specific intent to deceive the patent office. *Therasense v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290-91 (Fed. Cir. 2011) (en banc). Because inequitable conduct sounds in fraud, it is subject to the particularity requirement of Federal Rule of Civil Procedure 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-27 (Fed. Cir. 2009). On the "materiality" prong, a sufficient pleading must identify not only the allegedly relevant document, but also "where in those references the material information is found," "why the information is material," and "how an examiner would have used this information in assessing the patentability of the claims." *Id.* at 1329. The "intent" prong requires sufficient pleading of both knowledge and intent of a specific individual (not a group). *Id.* at 1328-29. The pleading must allow the court to reasonably infer that a specific individual "knew of the material information" (and not just being aware of the allegedly relevant reference in general, and not just "should have known" the information), and that an intent to deceive the PTO is "the single most reasonable inference able to be drawn from the evidence." *Id.*; *Therasense*, 649 F.3d at 1290.

IV. COUNTERCLAIM V FAILS BOTH IN SUBSTANCE AND FORM

A. The TRO/PI Proceedings Should Be Given Preclusive Effect on Issues of "Inequitable Conduct" and "Materiality"

This Motion comes after the TRO/PI proceedings in this case. In the Third Circuit, "findings made in granting or denying preliminary injunction have preclusive effect if the circumstances make it likely that the findings are sufficiently firm to persuade the court that there is no compelling reason for permitting them to be litigated again." *Trs. of the Gen. Assembly of*

the Lord Jesus Christ of the Apostolic Faith, Inc. v. Patterson, C.A. No. 21-634-KSM, 2024 WL1096527, at *1 (E.D. Pa. 2024); *see also Astrazeneca AB v. Dr. Reddy's Laboratories, Inc.*, 209 F. Supp. 3d 744, 753 (D. Del. 2016) (counterclaim of breach of contract dismissed based on the district court's TRO/PI decision). Such a preclusive effect depends on "whether the parties were fully heard, whether the court filed a reasoned opinion, and whether that decision could have been, or actually was appealed." *Astrazeneca*, 209 F. Supp. 3d at 753 (quoting *In re Brown*, 951 F.2d 564, 568 (3d Cir.1991)). A TRO/PI proceeding can generate preclusive effect even though a "substantial question," not "actual success," standard was applied. *Minard Run Oil Co. v. U.S. Forest Service*, 549 Fed. Appx. 93, 96 (3d Cir. 2013) (legal issues decided in a TRO/PI proceeding can become "law of the case"). Furthermore, "portions" of a preliminary injunction decision can be found to have reached the merits of the underlying claim. *Id.* (citing *ACLU v. Mukasy*, 534 F.3d 181, 188-90 (3d Cir. 2008)).

These factors compel giving this Court's "no substantial question on 'inequitable conduct'" and "FK PI not material" findings preclusive effect. (D.I. 61, at 10 ("the sterility and ready-to-use properties of the patented invention alone make it more likely than not that the '661 patent is not obvious over FK PI"), and 10 n. 3 (Amneal as "the party asserting inequitable conduct must show: that the applicant failed to disclose 'prior art that was material'" but Amneal failed to do so)). Preclusive effect should apply when a losing party "fails to identify an issue of fact that stands to be resolved, but rather continues to disagree with the legal conclusions of the preliminary injunction memorandum and order." *Trs. of Gen. Assembly of Lord Jesus Christ of the Apostolic Faith*, 2024 WL 1096527, at *2. Here, Amneal presented exactly the same documentary evidence during the TRO/PI proceedings as it is now alleging again in Counterclaim V. Amneal presented exactly the same arguments over the same FK PI reference as it is now again arguing in

Counterclaim V. Amneal cannot obtain more discovery to alter the Court's previous findings. If not dismissed, Amneal must relitigate the "inequitable conduct" issue before the Court, based on the same evidence, but under a much heavier burden.

1. Amneal's allegations are a repetition of the evidence it had presented during the TRO/PI proceedings

Amneal alleged that the FK PI reference "is also relevant prior art" to both patents-in-suit. (D.I. 91, at 47-48 ("Factual Background"), ¶ 23). Amneal alleged that the FK prior art concentrate product could be diluted to reach the same nutrient concentrations and aluminum contents as in the '661 patent. (*Id.* at 48, ¶¶ 24-25). Then, in Counterclaim V, Amneal expanded on the allegations above, stating that "the Named Inventors and Prosecutors" included information in a provisional application regarding "the FK PI and the amount of aluminum in the [FK product]." (*Id.* at 59, ¶ 97). Amneal went on to analyze the FK PI reference with a focus on the nutrient concentrations and aluminum contents that (in Amneal's view) could be achieved when the FK product is diluted, and with a passing reference to pH values. (*Id.* at 60-62, ¶¶ 101-110). That is the entirety of the basis for Amneal's allegations of "materiality" of the FK PI reference. Importantly, throughout the counterclaims, Amneal never alleged that the diluted FK concentrate product would be *sterile*.

During the TRO/PI proceedings, Amneal presented the same documents and made the same arguments, supported by a declaration from its technical expert Dr. Amiji. (D.I. 28 (Amneal Opposition Brief to the TRO/PI Motion), at 10-14; D.I. 29 (Amiji Decl.)).[4] The Court had evaluated all evidence Amneal presented, conducted a thorough analysis, and ruled on all

[4] Counterclaim V is essentially copied from Amneal's Opposition Brief to the TRO/PI Motion, (D.I. 28, at 12-14), with the text now rearranged into shorter paragraphs, and incorporating some cited contents from the supporting Amiji Declaration (*e.g.* the chart in Counterclaim V, D.I. 91, at 62-64, ¶ 110, is copied from the Amiji Declaration, D.I. 29, at 42-43, ¶ 135).

assertions that have now been repackaged by Amneal as Counterclaim V. The Court noted but *rejected* Amneal's contention that "FK PI discloses how to prepare and store the formulations in the RTU forms described in Claims 3 and 13 of the '661 patent." (D.I. 61, at 9). The Court noted that the FK product required "compounding … thereby increasing the risk of error and contamination." (*Id.* at 10). Indeed, Amneal admits in its Counterclaim V that the diluted FK product could only be stored for a limited time (4 hours at room temperature, 14 days when refrigerated). (D.I. 91, at 63 ("Storage and Stability" section from FK PI)). This *instability* after dilution again shows a lack of sterility, as the Court has found during the TRO/PI proceedings. Amneal now adds nothing more to the TRO/PI record, but merely repeats its contention, which should be rejected again. (D.I. 91, at 48, ¶ 24; 59-60, ¶¶ 99-101). Additionally, during the TRO/PI proceedings, Defendants argued "inherency" of pH values in diluted FK product, and now argue the same thing again. (D.I. 61, at 9; D.I. 91, at 62, ¶ 109). Then as now, Amneal did not contend that a diluted FK prior art product would be sterile. Amneal does not offer anything to disturb the Court's finding that "the sterility and ready-to-use properties of the patented invention alone make it more likely than not that the '661 patent is not obvious over FK PI." (D.I. 61, at 10).

Based on this "sterility" finding, and the documented fact that the PTO examiner issued the patents over the Koneru reference that is much closer to the claimed subject matter than FK PI is, the Court concluded that "it is likely that the '661 patent would have issued even if the applicant disclosed more details about FK PI to the examiner." (*Id.* at 10 n. 3). These rulings were made under the "substantial question" standard that is more lenient to *Amneal*. The same allegations Amneal is now making in its Counterclaims, even if presumed to be true, still did not address the "sterility" issue, and cannot possibly (let alone "plausibly") sustain a claim of inequitable conduct.

To summarize, on the "materiality" issue of the same FK PI reference Amneal is now exclusively relying upon for its "inequitable conduct" defenses and counterclaim, the same parties had been fully heard during the TRO/PI proceedings, and the same documents and arguments had been presented to the Court and carefully analyzed. The Court issued a well-reasoned opinion. Amneal could have appealed but chose not to. And now, Amneal might have wanted to allege facts to address the "sterility" issue, but it cannot. These circumstances clearly demonstrate that the Court's findings in the TRO/PI Opinion "are sufficiently firm" so that "there is no compelling reason for permitting them to be litigated again." *Trs. of the Gen. Assembly of the Lord Jesus Christ of the Apostolic Faith*, 2024 WL1096527, at *1; *Astrazeneca*, 209 F. Supp. 3d at 753.

2. Amneal's repetition of its "inequitable conduct" allegations is futile

The circumstances in this case compel preclusion on the "materiality" issue and dismissal of Amneal's attempt to relitigate the same issue. First, Amneal is not entitled to a jury trial on the "inequitable conduct" issues. "The defense of inequitable conduct in a patent suit, being entirely equitable in nature, is not an issue for a jury to decide." *Paragon Podiatry Lab'y, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993); *see also Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1358 (Fed. Cir. 2014) (bench trial on equitable defenses conducted before a jury trial on infringement and validity). On the requisite "but-for materiality" issue, Amneal is now alleging the same facts (based on documents, not involving any credibility determination) and making the same arguments to the same factfinder in the same tribunal—in hopes of getting reconsideration and a different result. Amneal made zero well-pled factual allegations that would suggest reconsideration.

Amneal could not possibly obtain any new facts through discovery to alter the outcome on the "materiality" issue. Amneal did not allege any new facts in its counterclaim. The Court has

already thoroughly compared the FK PI reference and the patent claims, and considered the prosecution histories, to reach the conclusion of "lack of materiality." Deposing the inventors or patent prosecutors would not change this conclusion. The materiality of a prior art reference is not affected by what they thought. *Therasense* 649 F.3d at 1290 ("Intent and materiality are separate requirements."). The Court has also considered the Reasons for Allowance given by the examiner. (D.I. 61, at 10 n. 3). A patent examiner, "in issuing or withholding patents … exercise quasi-judicial functions." *Butterworth v. U.S. ex rel. Hoe*, 112 U.S. 50, 67 (1884). Amneal is strictly forbidden to depose and ask the examiner about the FK PI reference, because that would be inquiring into "the examiner's bases, reasons, mental processes, analyses or conclusions." *W. Elec. Co., Inc. v. Piezo Tech., Inc.*, 860 F.2d 428, 432 (Fed. Cir. 1988) (no deposition for "insight into [the examiner's] mental processes in evaluating the application and pertinent references").

Given these circumstances and the nature and scope of relevant evidence that could be obtained to show "inequitable conduct," Amneal would not be able to improve upon its case on any "materiality" of FK PI through protracted litigation. No matter what Amneal would throw at the wall regarding the inventors' and/or the patent prosecutors' knowledge and intent, or how the patent examiner would have changed his mind upon seeing some information contained in FK PI, Amneal cannot get past these simple facts that were fully litigated and ruled upon by the Court: one, FK PI did not disclose the sterility and RTU properties in the patent claims; and two, the examiner had considered the "closest prior art" Koneru and still allowed both patents over it. (D.I. 61, at 10 n. 3; D.I. 29 at ¶¶ 79, 88 (block quotes from both Notices of Allowance)). The lack-of-materiality findings doom Amneal's "inequitable conduct" defenses and counterclaim. Therefore, Nivagen requests that Counterclaim V be dismissed *with prejudice*.

B. Counterclaim V Cannot Pass a *de novo* Review on the "Materiality" Issue

There are three glaring omissions in Amneal's pleading, highlighting the lack of materiality of FK PI to the prosecution of the Nivagen's patents. First, although Amneal targets both patents-in-suit, there is not a single factual allegation against the earlier '291 patent in Counterclaim V. All comparisons between FK PI disclosures and a patent claim are exclusively directed to the later '661 patent. (D.I. 91, at 48, ¶ 24; 59-60, ¶¶ 99-101 ("at least Claim 3 of the '661 patent"); 60-62, ¶¶ 102-109 (addressing the nutrient range, molar ratio, and pH range limitations found only in the '661 patent claims);[5] 62-64, ¶ 110 (chart on claims 1-3 of the '661 patent)). Other than conclusory statements such as "FK PI discloses the subject matter of at least one claim of the Asserted Patents," or "on information and belief, the patent examiner would have applied the FK PI alone … to render claim 11 of the '291 patent and claim 3 of the '661 Patent obvious," Amneal alleged nothing regarding what information in FK PI is material to the issuance of the '291 patent, or how such "material" information would have factored into the patent examiner's decision on the '291 patent. Note also that the '291 patent is the *earlier-filed and earlier-issued* patent in the family. Amneal did not, and cannot, allege some sort of retroactive "infectious inequitable conduct" stemming from the later prosecution of the '661 patent.

Second, Amneal still did not address the "sterility" issue. There are no factual allegations throughout its counterclaims to show that FK PI disclosed a sterile RTU product. Amneal made general allegations of patent invalidity by anticipation, such as "the FK PI discloses the subject matter of at least one claim of the Asserted Patents," and "the FK PI … is therefore ready-to-use as that term is defined in the Asserted Patents." (D.I. 91 at 59, ¶ 100, and 64, ¶ 111). These

[5] The relevant claims can be found in D.I. 91, at 46-47, ¶¶ 20-21.

allegations, however, are "conclusions … not entitled to the assumption of truth." *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 221 (3d Cir. 2011).

Third, Amneal did not mention the examiner's Reasons for Allowance, which typically would be front and center of any "inequitable conduct" analysis. (*See, e.g.*, *Shionogi & Co., Ltd. v. Norwich Pharmaceuticals, Inc.*, C.A. No. 23-161-MN, 2024 WL 4495288, at *4, ¶ 16 (D. Del. Sept. 23, 2024) (the Notice of Allowance showed that "[t]here is nothing to plausibly suggest that the outcome would have been different if the Examiner knew [the allegedly concealed information]."). Amneal did not advance any factual allegations to dispute that the Koneru reference (which is a U.S. patent) discussed by the examiner in the Reasons for Allowance disclosed "aluminum even less than about 17 mcg/L in the concentrate and 1 mM/mL phosphorus," and is much, much closer to the patent claims at issue than the FK PI disclosures are. (D.I. 61, at 10 n. 3 (discussing Koneru); *see also* D.I. 91 Ex. F (9/5/2024 Hr'g Tr.), at 15:12-19 (the Koneru patent actually issued over FK PI)). Ignoring the examiner's words on the record, Amneal again focused its analysis on aluminum and nutrient concentrations. (D.I. 91, at 60-64). Amneal then jumped to the conclusions that "the FK PI is not cumulative" and that "had the Named Inventors and Prosecutors disclosed the FK PI, [some claims] would not have issued." (*Id.* at 64-65, ¶¶ 115-117). Unsupported labels and conclusions carry no weight. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

In this case, materiality must be assessed under the exacting "but for" standard, because Amneal did not allege any "affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit." *Therasense*, 649 F.3d at 1291-92. Amneal must "explain both 'why' the information is material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims." *Exergen*, 575 F.3d at 1329-30.

Amneal utterly failed to provide any explanation on "but-for materiality"—especially in view of the examiner's Reasons of Allowance. Amneal did recite but-for materiality "on information and belief." (D.I. 91, at 65, ¶¶ 116-117). However, a statement "on information and belief" without supporting allegations "set[ting] forth the specific facts upon which the brief is reasonably based," is never sufficient under Rule 9(b). *Exergen*, 575 F.3d at 1330. Amneal offered no explanation on the sterility issue or why the examiner would set aside the "closest" Koneru reference and rely on FK PI instead. Amneal's "formulaic recitation" must be disregarded. *Bell Atl.*, 550 U.S. at 555; *Exergen*, 575 F.3d at 1326-27.

C. Counterclaim V Fails to Specify the "Who"

"[T]o plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen*, 575 F.3d at 1328. Counterclaim V is impermissibly vague as to "who" committed any improper acts. Amneal accused all six named inventors and four patent prosecutors, again "on information and belief." (D.I. 91, at 45, ¶ 15). Amneal then referred to "the Named Inventors and Prosecutors" throughout its Counterclaims. Nowhere did Amneal allege a single wrongful act done by a specific individual. Such blanket assertions of group wrongdoing are categorically insufficient to sustain an inequitable conduct count. *Exergen*, 575 F.3d at 1329 ("fail[ure] to name the specific individual associated with the filing or prosecution of the application … who both knew of the material information and deliberately withheld or misrepresented it" means a "fail[ure] to identify the 'who'"). The pleading must be specific as to "any specific individual," and not just a group. *Id.* at 1330 ("The pleading … provides no factual basis to infer that any specific individual … knew of the specific [material and omitted] information …."). For this reason alone, Amneal has failed to plead "inequitable conduct."

D. Counterclaim V Fails to Specify "What" Information Is Material, Known, and Concealed

Amneal failed to plead with particularity the "what," in two ways. First, Amneal did not identify what was the concealed material information. As discussed above, Amneal only compared alleged material information against the '661 patent claims in Counterclaim V. Some of such information was examined by the patent office, not concealed at all. Amneal pointed to the nutrient concentration and preparation information in FK PI. (D.I. 91, at 59, ¶¶ 99-100; 62-64, ¶ 110). However, Amneal also admitted that such information was "added to the '661 patent." (*Id.* at 59, ¶ 98). Indeed, the '661 patent specification, which was examined, *disclosed* the nutrient concentrations and preparation method of "a commercially available product." (D.I. 91 Ex. D (the '661 patent), at 1:49-52; 2:16-20). On the other hand, the molar ratio, aluminum content, and pH range information Amneal pointed to actually was *not disclosed* in FK PI, but requires the application of assumptions, "simple arithmetic," and inferences to the actual disclosures. (D.I. 91 at 60-62, ¶¶ 101-109). For example, Amneal spent a full page deriving the molar ratio information "using simple arithmetic." (*Id.* at 60-61, ¶¶ 102-105). Amneal had to derive the aluminum contents in diluted FK product using calculations that did not account for any aluminum contents introduced by the diluent and the containers during the dilution process.[6] (*Id.* at 61-62, ¶¶ 107-108). Amneal also acknowledged that "the FK PI does not expressly disclose the pH," but alleged

[6] Amneal's expert declarant Dr. Amiji explained this requisite assumption during the TRO/PI proceedings. (D.I. 29, at 41, ¶ 133 ("This also assumes that the … saline contributes 0 or negligible amount of aluminum, which in my opinion, is a reasonable assumption.")). For this Motion, Nivagen need *not* dispute the "reasonableness" of Dr. Amiji's assumption, but simply points out that, even according to Dr. Amiji, such an assumption must be made and applied to the actual disclosures in FK PI to derive the likely aluminum contents in a preparation made from diluting the FK concentrate product. FK PI contains no direct disclosures of aluminum contents in the diluted preparations made from adding large amounts of saline to the FK product in additional containers.

that the pH range would be "inherent[] … when [a solution is] prepared by the pharmacist according to the FK PI." (*Id.* at 62, ¶ 109). To summarize, Amneal's own allegations show that the allegedly concealed material information was either not concealed, or not in the FK PI reference.

Second, Amneal's conflation of what FK PI says and what one could allegedly understand from the disclosures made it impossible for Counterclaim V to satisfy the "what" pleading requirements when it comes to the knowledge and intent prong of "inequitable conduct." Amneal is required to specify which individual "knew of the specific material *information* contained in that reference." *Exergen*, 575 F.3d at 1330 (italics in the original, underlining added). Amneal utterly failed to identify any specific individual with knowledge of any concealed material information in FK PI. It could not have, because the molar ratio, aluminum content, and pH range "material information" was not even "contained in" FK PI. Furthermore, even if Amneal were to argue that someone among "the inventors and prosecutors" should be able to conduct the "simple arithmetic" calculations, make inferences, apply assumptions, and draw legal conclusions as Amneal had done to the FK PI disclosures, that argument would not save Counterclaim V from being dismissed. The law is clear that an adequate allegation must go beyond what an accused individual "reasonably should be aware." *Id.* The allegation must be specific as to which specific individual *was aware* of what material information "contained in a reference." *Id*. Amneal failed to make any such specific and factual allegations.

The failure to plead the "knowledge" prong with particularity also leads to a failure to plead any deceptive intent by a specific individual. Deceptive intent must be "the single most reasonable inference drawn from the evidence." *Therasense*, 649 F.3d at 1290. Without adequate allegations to show which specific individual knew what specific undisclosed material information contained

in the FK PI reference, it is impossible to draw any inference of deceptive intent on any individual, much less reaching "the single most reasonable inference."

E. The Second, Third, and Seventeenth Affirmative Defenses Should Be Stricken

As Nivagen has shown above, Defendants pled no facts to support their Second Affirmative Defense of "Inequitable Conduct." This defense is "insufficient" and should be stricken. Fed. R. Civ. P. 12(f); *Eagle View*, 325 F.R.D. at 102. Defendants based their Third Affirmative Defense of "unclean hands" on the same allegations in Counterclaim V. (D.I. 91, at 37). Therefore, this defense should also be stricken. *Shionogi*, 2024 WL 4495288, at *6 ("unclean hands" defense based on "inequitable conduct" allegations not meeting the pleading standard).

Defendants' Seventeenth Affirmative Defense of "patent misuse" is merely a "reference to a doctrine," without any indication of supporting factual allegations. (D.I. 91, at 39). "Patent misuse is the patentee's act of impermissibly broadening the physical or temporal scope of the patent grant with anticompetitive effect." *Finjan, Inc. v. ESET, LLC*, Case No. 17-cv-00183-CAB-BGS, 2017 WL 3149642, at *4 (S.D. Cal. 2017). Defendants, however, presented no allegations on how any such "broadening" of Nivagen's patents occurred. Unlike their "unclean hands" defense, Defendants did not even refer to any part of their pleading to support the "patent misuse" defense. Therefore, this defense is also insufficient as it "fail[s] to provide fair notice" to Nivagen and should be stricken. *Id.* at *2. To the extent the "patent misuse" defense is based on "inequitable conduct" allegations, it should be stricken along with the dismissal of Counterclaim V.

VI. COUNTERCLAIM VI DOES NOT STATE A VALID CAUSE OF ACTION OR POINT TO ANY AVAILABLE REMEDY

A. Amneal Cannot Recover Damages Caused by a Temporary Restraining Order

Counterclaim VI is styled as a "declaratory judgment" count, but Amneal is also seeking

unspecified damages. (D.I. 91, at 68, ¶ 137). It is unclear on which legal theory Amneal based its Counterclaim VI. Federal Rule of Civil Procedure 65(c) "strongly implies" a cause of action to recover on a bond after the case is decided on the merits, or a "rebuttable presumption that a wrongfully enjoined party is entitled to recover provable damages up to the bond amount." *Indivior Inc. v. Dr. Reddy's Laboratories S.A.*, Civ. No. 17-7111 (KM), 2020 WL 4932547, at *5 (D.N.J. 2020). However, such a cause of action requires the "existence of the bond," which is absent in this case. *Id.* at *6. Amneal cannot recover any damages under Rule 65.

Amneal therefore alleged "false and misleading statements" and "bad faith" in Counterclaim VI, seemingly attempting to trigger (without actually stating so) a "wrongful injunction common law remedy" to recover in excess of a bond. *See Globus Med., Inc. v. Vortex Spine, LLC*, C.A. No. 14-3105-CDJ, 2016 WL 5724453, at *1 n. 3 (E.D. Pa. 2016) (noting this "common law remedy" but refusing to extend it to cover TROs). However, this common law remedy is *not applicable to TROs*. *Id.* (dismissing with prejudice "wrongful enjoinment" claims based on TROs that lasted multiple months). In this case, Amneal was subject to both a TRO and a PI, which ran concurrently. (D.I. 61, at 23; D.I. 62, at ¶ 1; D.I. 70, at 2; D.I. 86). If Amneal were to proceed on a common law tort theory, it would not be able to prove that any damages were caused by a wrongful PI as opposed to the TRO.

Either way, Counterclaim VI fails to state a claim upon which relief can be granted.

B. Counterclaim VI Did Not Plausibly Set Forth A Causative Link Between Any Alleged Misrepresentations and the Preliminary Injunctive Relief

This case does not present an occasion to create a common law tort cause of action to cover "wrongful TROs." Amneal's allegations, even if taken as true (which they are not), still do not plausibly describe a causative link between any of the "false and misleading statements" Nivagen

allegedly had made to the Court, on one hand, and the "damages caused by the wrongful enjoinment" Amneal allegedly suffered, on the other hand. (D.I. 91, at 68, ¶ 137).

The alleged "misrepresentations" in Counterclaim VI fall in two categories. First, "on information and belief," Amneal alleged that Nivagen "misrepresented ownership of the NDA," the NDA approval status, and product launch timing. (*Id.* at 66, ¶¶ 123-125; 67, ¶¶ 127-130). Second, Nivagen allegedly "inflated its alleged damages." (*Id.* at 66, ¶ 126; 67-68, ¶¶ 131-134). Amneal concluded that these misrepresentations "relat[e] to irreparable harm," and "contributed to the wrongful enjoinment of Amneal …." (*Id.* at 66, ¶ 122; 68, ¶ 135). However, there was not a single factual allegation to show causation. None of the alleged misrepresentations contributed to the Court's finding of "irreparable harm."

Regarding the first category, the Court was well aware of the collaboration between Nivagen and Fresenius Kabi, including who owns the NDA on Nivagen's RTU product. (D.I. 91 Ex. F (9/5/2024 Hr'g Tr.), at 7:22-25 ("[Fresenius Kabi] actually had a NDA and the Nivagen product is filed as a supplemental to that NDA")). The Court was also aware that Nivagen would be manufacturing its RTU product upon FDA approval, and Fresenius Kabi would be dealing with buyers directly. (*Id* at 44:9-45:2). The Court addressed the "contingencies" including the FDA potentially denying or delaying the approval of the Nivagen RTU product "for some reason." (*Id.* at 6:13-14; 7:11-12). Nivagen frankly admitted that "we don't have anything that we can show that approval is … on a certain date," and that "we don't know exactly when." (*Id.* at 6:12; 8:1). Instead, Nivagen argued, and the Court credited, that the irreparable harm would come from the "first mover advantage," meaning that a first mover (in this case Amneal) in a nascent market would be able to sign long-term contracts with the limited number of buyers in the market, get "locked in," and cause "spoliation of the relationship with these buyers [for Nivagen]." (*Id.* at 7:2-

10; 18:18 – 19:7; 21:3-13). Nivagen emphasized that Amneal would gain the first-mover advantage at *Amneal's* product launch, regardless of the exact timing of *Nivagen's* subsequent product launch. (*Id.* at 7:7-10).

After the motion hearing, the Court credited "the loss of first mover advantage" as the basis for "irreparable harm." (D.I. 61, at 20-24). On this issue, the Court did not rely on the exact timing of Nivagen obtaining FDA approval, or the identity of the NDA owner. Instead, the Court recognized that a first mover would "establish long-lasting relationships" with buyers in the market. (*Id.* at 22-23). A first mover would also build a reputation as an innovator in the field. (*Id.* at 23-24). Amneal has not alleged in its Counterclaim VI how any "misrepresentations" in the first category actually related to the Court's opinion, or "contributed" to the TRO/PI decision.

Regarding the second category, the Court did cite parts of Mr. Shukla's declaration regarding Nivagen's expectation "to make $45-50 million in sales … with an expected profit of 60% gross margin …." (*Id.* at 17-18). However, this citation appeared in the section of the Court's opinion on "loss of market share and profits," and the Court ultimately concluded that Nivagen had not shown any such loss to be irreparable. (*Id.* at 18). These numbers from Mr. Shukla's declaration plainly did not contribute to the TRO/PI decision. The Court's analysis on the "first-mover advantage," on the other hand, did not cite to or rely on any expected sales and profit margin numbers. (*Id.* at 20-24). The first-mover advantage is based on "long-lasting relationships with early customers," and "reputation [as an innovator]." (*Id.* at 22-23). Amneal has not alleged any misrepresentations by Nivagen regarding a first mover's ability to establish long-term relationships with customers or gain reputation as an innovator—which were the actual bases for the Court's decision finding "irreparable harm."

To summarize, the allegations in Counterclaim VI, even if true (which they are not), cannot create a new tort cause of action, or generate a causative link based on the previous proceedings in this case. Therefore, Nivagen respectfully requests that Counterclaim VI be dismissed *with prejudice*.

VII. CONCLUSION

For the foregoing reasons and any reasons the Court deems just and proper, Nivagen Pharmaceuticals, Inc. respectfully requests that the Court dismiss with prejudice Amneal Pharmaceuticals LLC's Counterclaims V and VI, and strike Defendants' Second, Third, and Seventeenth Affirmative Defenses.

Respectfully submitted,

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